



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE

**Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621
(510) 635-5000**

**September 22, 2004
9:30 a.m. – 12 noon
*Boardroom 5, Building 5***

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may also attend and comment.

- A. Call to Order** **9:30 a.m.**
- B. Proposed Omnibus Legislative Changes for 2005 Related to:**
- Elimination of the Rules of Professional Conduct (Bus. & Prof. Code sec. 4005)
 - Clarification of Designated Representative Requirements for Wholesalers (Bus. & Prof. Code sec. 4053)
 - Technical Updates to Various Licensing Provisions (Bus. & Prof. Code sec. 4127.5, 4205 and 4206)
 - Fee Schedule Update (Bus. & Prof. Code sec. 4400)
- C. Proposed Legislative Change to the Pharmacist License Renewal Process Related to the Continuing Education Requirement (Bus. & Prof. Code sec. 4231 and 4232)**
- D. Proposed Regulation Change to Implement SB 1913 Related to Foreign Pharmacy School Graduates and the Certification Process by the Foreign Pharmacy Graduate Examination Committee (CCR, title 16, sec. 1720.1)**
- E. Proposed Regulation Change to Implement SB 1913 Related to the Application Process for the Pharmacist Licensure Examination and Intern Experience Requirements (CCR, title 16, sec. 1728)**
- F. Proposed Omnibus Regulation Changes to Implement SB 1913 and Update of Licensing Requirements**
- Abandonment of Application Files, Failure to Pay Fee for Pharmacist Licensure and Failure to take Pharmacist Licensure Examination Within One Year (CCR, title 16, sec. 1706.2)
 - Recognized Schools of Pharmacy (CCR, title 16, sec. 1719)
 - Application for Examination and Licensure (CCR, title 16, sec. 1720)
 - Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts (CCR, title 16, sec. 1725)
 - Supervision of Intern Pharmacists (CCR, title 16, sec. 1726)

Deletion of Intern Pharmacist Requirements (CCR, title 16, sec. 1727)
Update of Fee Schedule (CCR, title 16, sec. 1749)
Deletion of Fee Schedule for a Warehouse License (CCR, title 16, sec. 1750)

- G. Proposed Regulation Change to Update Continuing Education Provisions (CCR, title 16, sec. 1732 – 1732.7)**
- H. Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Pharmacist Jurisprudence Examination (CPJE) - Status on the Restructuring of the Competency Committee**
- I. Discussion on How the Board of Pharmacy Can Improve and Facilitate Communications with Licensees**
- J. Report on Staff Discussions with Board of Corrections Regarding Pharmacy Services in City and County Jails and Juvenile Facilities**

Adjournment

12 noon

Meeting materials will be on the board's Web site by September 15th

AGENDA ITEM B

Memorandum

To: Licensing Committee

Date: September 8, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Omnibus Items for 2005

Sections 4005 and 4206 – Rules of Professional Conduct

Section 4206 [formerly Section 4008.3] requires that each pharmacist sign off on the “rules of professional conduct” as part of their application (a copy of this document is attached for your reference). This requirement was established in 1959 and was subject to technical amendments in 1965 and 1971. However, this requirement has remained essentially unchanged since that date. Subdivision (c) Section 4005 [formerly Section 4008.2] authorizes the board to adopt these “rules of professional conduct” through the rulemaking process specified in the Administrative Procedures Act.

The current “rules of professional conduct” is a listing of selected regulation sections [1714, 1715.6, 1717, 1761, 1764, 1765, 1793.1] and a statement that the applicant agrees to abide by these regulations. The statute appears to allow the board to establish “rules of professional conduct” above and beyond those included in the board’s statutes and regulations. However, no such document has existed in the memory of any current board staff which extends back over approximately 25 years.

This requirement provides no additional value for public protection as the existing law requires the board’s licensees to comply with the specified sections and all other applicable sections of the Pharmacy Law. Accordingly, staff is suggesting the repeal of Section 4206, and the relevant portion of Section 4005, to streamline the pharmacist licensure process.

Section 4053 -- Exemtees

The existing section addresses the issuance of “certificates of exemption” to individuals handling dangerous drugs and dangerous devices in wholesale facilities. Senate Bill 1307 changes current board terminology to reflect usage in other states and names these individuals “designated representatives.” The change proposed here makes the section easier to understand and makes no substantive change in law. The proposed language parallels other sections that authorize the issuance of a personal license.

Section 4127.5 – Fee Exemption

This section sets the fee for the issuance of a sterile compounding license. Existing board practice based on Section 4400 (a) is to exempt government owned and tribally owned

pharmacies from this fee. The proposed amendment clarifies that this exemption applies to sterile compounding licenses as well.

Section 4205 -- Hypodermic Permits

This section details the application requirements for hypodermic licenses. The proposed changes make minor technical changes to eliminate obsolete code section references.

Section 4400 – Fee Provisions

The proposed amendments to Section 4400 make a range of changes as follows:

1. Eliminates an obsolete reference to medical device retailers.
2. Combines the application and issuance fee for exemptee licenses.
3. Eliminates the fee for approval as an accrediting entity for continuing education consistent with other proposals.
4. Eliminates the fee for the foreign graduate application consistent with other proposals.
5. Makes a number of other technical changes to the section.

Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; and pertaining to the sale of drugs by or through any mechanical device.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

~~(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.~~

~~(d)~~ The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Section 4053 of the Business and Professions Code is amended to read:

4053. (a) ~~Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a~~ Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall adequately safeguard and protect the public health and safety in the handling, storage and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer. ~~, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).~~

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

- (D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
- (E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.
- (4) The board may, by regulation, require training programs to include additional material.
- (5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
- (c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
- (d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
- (e) This section shall become operative on January 1, 2006.
- (f) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

Section 4127.5 of the Business and Professions Code is amended to read:

4127.5. The fee for the issuance of a non-governmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).

Section 4205 of the Business and Professions Code is amended to read:

4205. (a) A license issued pursuant to Section 4110, 4120, ~~4130~~, 4160, or 4161 shall be considered a license within the meaning of Section 4141.
- (b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use ~~for animals and poultry~~.
- (c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of ~~this article~~ Article 9 of this chapter.
- (d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.
- (e) A license shall be renewed annually and shall not be transferable.
- (f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

Section 4206 of the Business and Professions Code is repealed.

~~4206. The rules of professional conduct adopted by the board shall be printed as a part of the application for licenses and every applicant shall subscribe thereto when making an application.~~

Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
- (a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).
 - (b) The fee for a nongovernmental pharmacy ~~or medical device retailer~~ annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).
 - (c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).

(d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).

(f) The fee for a non-governmental wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).

~~(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars (\$100).~~

(1) The fee for the application, investigation and issuance of an exemptee license pursuant to Section 4053 shall be one-hundred eighty-five dollars (\$185) and may be increased to two-hundred fifty dollars (\$250). If the applicant is not issued an exemptee license, the board shall refund seventy-five dollars (\$75) of the fee.

(2) The fee for the annual renewal of an exemptee license shall be one-hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150).

~~(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).~~

(1) The fee for the application, investigation and issuance of an exemptee license for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two-hundred fifty dollars (\$250). If the applicant is not issued an exemptee license, the board shall refund one-hundred dollars (\$100) of the fee.

(2) The fee for the annual renewal of an exemptee license for a veterinary food-animal drug retailer shall be one-hundred fifty dollars (\$150).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

~~(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).~~

~~(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.~~

~~(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).~~

~~(n)~~

(l) The fee for an intern pharmacist license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

~~(o) (m) The board may, by regulation, provide for the waiver waive or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding-regular renewal date.~~

~~(p) (n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).~~

~~(q)~~ (o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).

~~(r)~~ (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

~~(s)~~ (q) The fee for any applicant for a non-governmental clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

~~(t)~~ (r) The board shall charge a fee for the processing and issuance of a license registration to a pharmacy technician and a separate fee for the biennial renewal of the license registration. The ~~registration~~ license fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).

~~(u)~~ (s) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).

~~(v)~~ (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).



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ARNOLD SCHWARZENEGGER, GOVERNOR

RULES OF PROFESSIONAL CONDUCT

(Please Sign and Return to the Board)

1714 OPERATIONAL STANDARDS AND SECURITY

- (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

1715.6 REPORTING DRUG LOSS

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

1717. PHARMACEUTICAL PRACTICE

- (a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided (1) a patient med pak is reused only for the same patient; (2) no more than a one-month supply is dispensed at one time; and (3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
- (b) In addition to the requirements of section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:
 - (1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the preceptor before they are dispensed.
 - (2) The brand name of the drug or device; or if a generic drug is dispensed, the distributor's name which appears on the commercial package label; and
 - (3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
 - (4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
- (c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.
All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing or furnishing.
Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of the subsection.
- (d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in the State other than California in accordance with Business and Professions Code section 4005.
- (e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by a

patient or at the hospital, institution, medical office or clinic at which the patient is present. The Board may in its sole discretion waive this application of the regulation for good cause shown.

- (f) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, Section 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription, identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716.

Information maintained by each pharmacy shall at least include:

- (1) Identification of pharmacist(s) transferring information;
 - (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
 - (3) Original date and last dispensing date;
 - (4) Number of refills and date originally authorized;
 - (5) Number of refills remaining but not dispensed;
 - (6) Number of refills transferred.
- (g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initialing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

1761. ERRONEOUS OR UNCERTAIN PRESCRIPTIONS

- (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity, or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

1764. UNAUTHORIZED DISCLOSURE OF PRESCRIPTIONS

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.

1765. COMMISSIONS, GRATUITIES, REBATES

An unlawful commission, gratuity or rebate prescribed by this article and Business and Professions Code Section 650 includes the rendering by a pharmacist or pharmacy of consultant pharmaceutical services such as those required pursuant to Title 22, Division 5, Chapters 3 and 4 (skilled nursing facilities and intermediate care facilities) to a licensed health care facility for no cost, nominal cost, or below reasonable cost, if that pharmacist or pharmacy obtains patients, clients or customers and/or their prescription order from that licensed facility or entity.

The determination of the value of consultant pharmaceutical services rendered shall include, but not be limited to, the value of all goods and services furnished by the pharmacist or pharmacy to a licensed health care facility.

1793.1 DUTIES OF A REGISTERED PHARMACIST

Only a registered pharmacist, or an intern pharmacist acting under the supervision of a registered pharmacist, may:

- (a) Receive a new prescription order orally from a prescriber or other person authorized by law.
- (b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
- (c) Identify, evaluate and interpret a prescription.
- (d) Interpret the clinical data in a patient medication record system or patient chart.
- (e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
- (f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
- (g) Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
- (h) Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.
- (i) Perform all functions which require professional judgement.

I hereby agree to abide by the Rules of Professional Conduct as they may, from time to time, be revised by the California State Board of Pharmacy.

Print Name of Applicant _____

Signature of Applicant _____ **Date** _____

AGENDA ITEM C

Memorandum

To: Licensing Committee

Date: September 8, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Continuing Education Legislation

In the course of reviewing the statutes and regulations governing continuing education (CE) for pharmacists, staff also reviewed existing board processes for license renewal related to continuing education. The proposed changes attached to this memo are the product of that review. The proposal makes the following substantial changes to existing law:

1. Change references to “pharmaceutical education” to “pharmacy education.”

Discussion: This change was requested by CPhA along with numerous changes to existing CE regulations being discussed at this meeting.

2. Eliminate the board’s authority to establish the continuing education required by regulation and establish the current 30 hour continuing education requirement in statute.

Discussion: Current statute allows the board to set the number of CE hours required for renewal by regulation up to a maximum of 30 hours. Current board regulations specify the maximum 30 hours for renewal. Given this situation, there is no need for both statute and regulation to set the CE hours requirement.

3. Modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license.

Discussion: Existing statute exempts recent graduates from complying the CE renewal requirement. Given that pharmacists moving to California from other states who graduated from pharmacy school more than two years ago must study for both the NAPLEX and the CPJE to become licensed, staff believes that such preparation for the exams should be given equal weight as 30 hours of CE. The revised language would exempt both recent graduates and those becoming licensed in California substantially after graduation.

4. Specifies that pharmacists who fail to provide proof of completed CE (currently proof is a signed statement attesting to completion) within 60 days of the renewal date will be issued an inactive license.

Discussion: Currently pharmacists who fail to certify their continuing education credits but do pay the renewal fee are unable to practice but have an uncertain license status. Their license is not delinquent (because the fee has been paid) and can remain in this uncertain status

indefinitely. Their license is not subject to subsequent renewal. Existing law provides for an inactive pharmacist license which prohibits the licensee from practicing but is subject to renewal. A pharmacist with an inactive license can reactive that license at any time upon payment of the renewal fee and providing evidence of the required 30 hours of CE. Issuing an inactive license to these CE delinquencies will resolve the ambiguity of their license status and ease the administrative burden to the board for processing these renewals.

Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license issue any renewal certificate unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy pharmaceutical education during the two years preceding the application for renewal. The continuing education required by this article shall consist of the number of clock hours, not to exceed 30 clock hours, designated by regulation adopted by the board. This section shall not apply to licensees during the first two years immediately following their graduation from a college of pharmacy or department of pharmacy of a university recognized by the board.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education within 60 days of the license expiration date, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704 of the Business and Professions Code.

Section 4232 of the Business and Professions Code is amended to read:

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional ~~pharmaceutical~~ pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

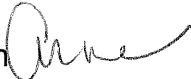
(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

AGENDA ITEM D

Memorandum

To: **Licensing Committee**

Date: **September 13, 2004**

From: Anne Sodergren 
 Board of Pharmacy

Subject: Proposed Regulation Changes to Implement SB 1913 – Foreign Pharmacy Graduate Requirements

Section 4200 (a)(2)(B) requires an applicant for licensure as a pharmacist who has graduated from a foreign pharmacy school to, among other things, receive a grade satisfactory to the board on an examination designed to measure equivalency. SB 1913, currently on the governor's desk, if enacted a graduate from a foreign pharmacy school will be required to obtain full certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC).

This certification is designed to assess the educational equivalence of foreign pharmacy graduates. Forty-six states currently require FPGEC certification.

Certification requirements include:

- Graduation from a pharmacy program that requires at least a four-year curriculum if education was completed prior to January 1, 2003, or a five-year curriculum after January 2003. An evaluation of the academic program is complete to ascertain whether it meets certain minimum criteria of length and content.
- Proof of licensure in the country the candidate earned the pharmacy degree.
- Passing scores on the Foreign Pharmacist Graduate Equivalency Examination, Test of Spoken English (50, the same as the board's requirement) and Test of English as a Foreign Language.

As a result of this change, the board will no longer require the submission of a foreign graduate application or complete evaluations of foreign transcripts.

To ensure consistency with the statutory changes, the board is proposing the attached amendment to CCR 1720.1. The proposed amendment clarifies that the certification obtained by the FPGEC satisfies the educational requirements detailed in Section 4200.

The board is preparing a letter to those with a foreign graduate application on file who have not yet been licensed as a pharmacist, notifying them of these changes that will take effect January 1, 2005.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Examination Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a).

~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~

~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section Sections 851 and 4200, Business and Professions Code.

AGENDA ITEM E

Memorandum

To: Licensing Committee

Date: September 13, 2004

From: Anne Sodergren
Board of Pharmacy



Subject: Proposed Regulation Changes to Implement SB 1913 – Application Process for the Pharmacist Licensure Examination and Intern Experience Requirements

As part of the board's ongoing efforts to streamline application requirements, a number of changes to the intern pharmacist program have been pursued. Section 4209 is a new section added to statute detailing the intern requirements an applicant must satisfy before applying for the pharmacist licensure examinations. This statute in part moves the intern requirements previously only listed in the board's regulation CCR 1728.

To clarify the specific intern requirements, the board is proposing the attached amendment to CCR 1728. The proposed amendments change the intent of the regulation from listing intern requirements to also detailing requirements for the examination.

Specifically the following changes are made:

- Remove the first year maximum cap on intern hours, (currently 250 hours).
- Remove the seven required areas of experience listed and instead require that the experience satisfy the requirements for the introductory and advanced pharmacy practice experienced established by the ACPE.
- Require proof that the applicant graduated from a recognized school of pharmacy.
- Require both a state and federal criminal history.

To implement these changes, the board is revising procedures and affidavits.

§1728. Intern Experience--Requirements for Examination. Licensure:

~~(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure:~~

~~(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.~~

~~(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.~~

~~(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.~~

~~(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:~~

~~(1) Receiving and interpreting the prescription;~~

~~(2) Patient medication profiles;~~

~~(3) Prescription preparation;~~

~~(4) Consultation;~~

~~(5) Record keeping;~~

~~(6) Over the counter products;~~

~~(7) Drug information.~~

~~(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~

~~(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by Section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code Section 144.

- (4) A signed copy of the examination security acknowledgment.
- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.
- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005 and 4114, Business and Professions Code.
Reference: Sections 144, 851, 4114 and 4200, Business and Professions Code.

AGENDA ITEM F

Memorandum

To: Licensing Committee

Date: September 9, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: SB 1913 Regulation Clean-up

Senate Bill 1913 and the adoption of the NAPLEX requires the board to alter existing regulations relating to the pharmacist licensing process to reflect the new statutes and to streamline board operations. Below is proposed regulation language developed by to staff to update board regulations. Many of the changes are minor or technical but a number of the changes are substantive.

Section 1706.2 – This relocates existing provisions regarding the abandonment of applications into the section addressing that issue.

Section 1719 – This section recognizes schools of pharmacy that are accredited by or granted candidate status by the ACPE [this change was previously approved by the board]. The provisions relating to foreign graduates have been eliminated because of SB 1913 which requires all foreign graduates must be FPGEC certified which includes the existing requirements.

Section 1720 – This section is changed to reflect the current exam structure.

Section 1725 – This section is changed to conform to Section 1719.

Section 1726 – This section is changed to eliminate reference to "preceptor." Preceptor is no longer a relevant term as Interns may be supervised by any pharmacist in good standing.

Section 1727 – This section is repealed. Similar provisions have been added to the Business and Professions Code.

Section 1749 – This section is amended to make numerous technical changes. The amendments also include the elimination of the foreign graduate application fee consistent with the changes made to foreign graduate licensing requirements [see item D on this agenda]. The amendments also eliminate the fee for registering continuing education accreditation entities to be consistent with changes proposed for continuing education regulations [see item G on this agenda].

Section 1750 – This section is repealed as the underlying statute was repealed in 2003.

§1706.2. Abandonment of Application Files.

- (a) An applicant for a permit license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy manufacturer, wholesaler, supplier, out-of-state distributor, or clinic, medical device retailer or warehouse of a medical device retailer who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.
- (b) An applicant for a pharmacy technician license registration who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
- (c) An applicant who fails to pay the fee for licensure as a pharmacist required by Section 1749(f) within one year after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
- (d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within twelve months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4029, 4033, 4034, 4037, 4043, 4110, 4112, 4115, 4120, 4127.1, 4160, 4190 and 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

Article 3. ~~Licentiates in Pharmacy~~ Pharmacist Candidates

~~§1719. Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

~~(a) Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~

~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~

~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 851, 4005 and 4200 of the Business and Professions Code.

§1720. Application for Examination and Licensure.

- (a) An application for the pharmacist licensure examinations examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.
- (b) The fee required by section 1749, subdivision (d) shall be paid for each application for initial examination and for any application to retake the examination described in Section 4200.2 of the Business and Professions Code. The fee is nonrefundable.
- ~~(c) An applicant who fails to pay the fee required by section 1749, subdivision (f) within one year after being notified by the board of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~
- (d) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
- ~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

NOTE:

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

- (a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy recognized school of pharmacy. ~~approved by the American Council on Pharmaceutical Education or recognized by the board.~~
- (b) A final examination must be a part of the course of study.
- (c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

§1726. ~~Preceptor-~~ Supervision of Intern Pharmacists.

- (a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision. ~~A preceptor is a pharmacist~~

~~registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.~~

~~(b) The preceptor pharmacist supervising an intern pharmacist shall supervise the intern's activities to provide the experience necessary to make for the intern pharmacist to become proficient in the practice of pharmacy. provision of pharmaceutical services.~~

~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1727. Intern Pharmacist.

~~(a) An intern pharmacist is a person who holds a valid intern card.~~

~~(b) An intern card shall be issued for a period of:~~

~~(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.~~

~~(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.~~

~~(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.~~

~~(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.~~

~~(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:~~

~~(1) Persons who have not completed experience requirements.~~

~~(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.~~

~~(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.~~

~~(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with Section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a permit to conduct a pharmacy license is three hundred forty dollars (\$340). The fee for the annual renewal of said permit pharmacy license is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).

(b) The fee for the issuance of a temporary pharmacy permit is one hundred seventy-five dollars (\$175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars (\$50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars (\$50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars (\$25). (d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars (\$155).

(e) The fee for regrading an examination is seventy-five dollars (\$75).

(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars (\$115).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars (\$115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents (\$57.50).

(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars (\$90). The penalty for failure to renew is forty-five dollars (\$45).

(j) The fees for a certificate of exemption under the provisions of sections 4053, or 4054 and ~~4133~~ of the Business and Professions Code are as follows:

(1) For the application and investigation of the applicant, the fee is seventy-five dollars (\$75).

(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars (\$110). The penalty for failure to renew is fifty-five dollars (\$55).

(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for ~~registration as an intern pharmacist~~ license ~~or extension of the registration~~ is sixty-five dollars (\$65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars (\$10).

(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars (\$30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars (\$60).

(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars (\$100). The penalty for failure to renew is fifty dollars (\$50).~~

(o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(p) ~~The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars (\$165).~~

(q) ~~(o)~~ The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars (\$340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).

(r) ~~The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars (\$170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents (\$87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents (\$43.75).~~

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4130, 4196, 4200(e), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403, Business and Professions Code.

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars (\$100). The penalty for failure to renew is twenty five dollars (\$25).~~

Authority cited: Section 4005, Business and Professions Code; and Section 11127, Health and Safety Code. Reference: Section 11127, Health and Safety Code.

AGENDA ITEM G

Memorandum

To: Licensing Committee

Date: September 9, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Continuing Education Regulations

Below is a draft of changes to board regulations governing continuing education. CPhA provided the board with suggested amendments to these regulations to update terminology used by the continuing education community. The attached draft includes both the CPhA amendments and a reorganization and clean-up of the existing regulations. The changes represent a substantial reorganization of existing regulatory provisions but there are relatively few changes in the substance of the regulations. The draft is footnoted to indicate the location of existing provisions that were moved and to note those provisions that were altered or eliminated.

Article 4. Continuing Education

§1732. Definitions.

As used in this article:

- (a) ~~An accreditation~~ “Accreditation agency” means is an organization which evaluates and accredits providers of continuing pharmaceutical education for pharmacists, ~~monitors the quality of their educational activities, and audits continuing education coursework.~~
- (b) ~~The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.~~¹
- (c) ~~The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.~~²
- (d) ~~A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.~~³
- (e) ~~An hour consists of “Hour” means at least 50 minutes of contact time.~~
- (c) “Provider” means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved ~~by the Board as continuing education and accreditation agencies:~~

¹ Duplicates provision in Section 1732.05 (a).

² Duplicates provision in Section 1732.05 (a).

³ “Non-recognized provider” is eliminated. Providers are accredited by accreditation agencies or specific courses are accredited by the board.

- (1) ~~The Accreditation Council for Pharmacy Education. American Council on Pharmaceutical Education~~
- (2) ~~The Pharmacy Foundation of California.~~⁴ ~~Accreditation Evaluation Service of the California Pharmacists Association~~
- (b) ~~Upon written application to the Board, any other organization will be approved by the board~~⁵
 if: Accreditation agencies shall:
- (1) ~~the organization submits a plan demonstrating that it has the capacity to evaluate~~ Evaluate ~~each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of Section 1732.1.~~
 following criteria:
- (A) ~~Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.~~⁶
- (B) ~~Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.~~⁷
- (C) ~~Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.~~⁸
- (D) ~~Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.~~⁹
- (E) ~~When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.~~¹⁰
- (F) ~~Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~
- ~~1. the educational goals and specific learning objectives of the program.~~
 - ~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~
 - ~~3. the speakers and their credentials.~~¹¹
- (G) ~~An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre and post testing, pre-testing along with group discussion and critique of answers, patient case study discussions and problem-solving exercises. The provider shall also develop a mechanism for each participant to evaluate the continuing education course.~~¹²
- (H) ~~Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~

⁴ Changed to reflect the reorganization of AES into the Pharmacy Foundation of California.

⁵ This draft explicitly recognizes two accrediting agencies and would require a regulation change to add new accrediting agencies. The board has not approved a new accrediting agency in many years (if ever).

⁶ Eliminated because it is repetitive of Section 4232 and Section 1732.3.

⁷ Moved to section 1732.3 relating to CE course requirements.

⁸ Moved to section 1732.3 relating to CE course requirements.

⁹ Moved to section 1732.3 relating to CE course requirements.

¹⁰ This provision is eliminated as it is unnecessary.

¹¹ Moved to Section 1732.1 relating to CE providers.

¹² Moved to Section 1732.3 relating to CE course requirements.

1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,
2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,
3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.¹³

(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.

1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.
2. For home study and other mediated instructional approaches—acceptable documentation of participation includes:
 - a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;
 - b. in the case of study groups, the successful completion of the program may be attested to by all participants; or
 - c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.¹⁴

(2) The organization agrees to perform the following: (A) Maintain a list of the name and address names and addresses of the persons designated as person responsible for the provider's C.E. continuing education program. The accreditation agency shall require that any change in the designated responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of such change.

(B) Notify the Board of

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(C)

(4) Respond to complaints from the board Board, providers or from California pharmacists concerning activities of any of its approved accredited providers or their coursework.

(D)

(5) Review at least a ten percent (10%) sample of coursework, as determined by the Board, but not less than ¹⁵ one course per year offered by each provider approved accredited by the agency for compliance with the agency's requirements and requirements of the board Board and, on request, report the findings of such reviews to the board Board.

(E)

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board Board; and

(F)

¹³ Moved to Section 1732.1 and simplified.

¹⁴ Moved to Section 1732.1 and simplified.

¹⁵ Change requested by CPhA to conform with existing standards in the continuing education community.

- ~~(7) Verify the attendance of licentiates completion at of a specific continuing education course by an individual pharmacist presentations upon request of this article, the Board.~~
- (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of its approval as an accreditation agency by the board Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.1. Requirements for Recognized Accredited Providers.

- (a) ~~Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses. No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to Section 1732.2.~~

- (b) Providers shall ensure that each continuing education course complies with the requirements of Section 1732.3.

~~Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.~~

- (c) ~~The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice.¹⁶~~

~~All continuing education coursework shall be:~~

- ~~(1) accurate and timely;¹⁷~~
- ~~(2) presented in an orderly fashion conducive to the learning process;¹⁸~~
- ~~(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;¹⁹~~
- ~~(4) specifically applicable and pertinent to the practice of pharmacy; and~~
- ~~(5) based on stated educational goals and objectives.²⁰~~

- ~~(d) All providers~~

- (c) Providers shall furnish certificates of completion statements of credit²¹ to all participants that complete a continuing education course. enrollees. The certificate statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

- ~~(e)~~

- ~~(d) Each recognized provider shall notify the accreditation agency, on forms approved by the board, within at least 15 days in advance of the first time each new C.E. course is offered or presented.~~

- ~~(f) All providers~~

- (c) Providers shall maintain records of attendance at or completion of their continuing education courses programs for four (4) years.

¹⁶ Recast and moved to Section 1732.3.

¹⁷ Eliminated as redundant since CE courses must be "relevant" to the practice of pharmacy and outdated or inaccurate information would not meet the relevance standard.

¹⁸ Eliminated because the provision is unreasonably vague.

¹⁹ Moved to Section 1732.3.

²⁰ Eliminated as repetitive of other sections requiring specific learning objectives.

²¹ Change requested by CPhA to conform to current terminology.

(f) Providers shall include the following information in promotional materials regarding continuing education courses:

- (1) Provider's name.
- (2) The number of hours awarded for completion of the course
- (3) The course's date of expiration
- (4) The provider number assigned by the accreditation agency.
- (5) The name of the provider's accrediting agency.
- (6) The learning objectives of the program.
- (7) The nature of the targeted audiences that may best benefit from participation in the program.
- (8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.2. Coursework from Non-Recognized Providers. Board Accredited Continuing Education.

~~(a) Non-recognized providers or pharmacists~~ Individuals may petition the ~~Board~~ board to allow continuing education credit for specific coursework which is not offered by a ~~recognized~~ provider but meets the standards of ~~Section 1732.3. relevance to pharmacy practice and educational quality, as set forth in subdivision (e) of section 1732.1.~~

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.3. Coursework Approval for Providers. Requirements for Continuing Education Courses

(a) Unless denied by the accreditation agency upon audit, all coursework offered by ~~California recognized providers is considered as approved in California.~~ may be used to satisfy the continuing education required by Section 1732.5.

(b) On a random basis ~~established by the Board~~ or in response to ~~complaints about a particular provider or~~ requests by the ~~board~~ Board, the accreditation agency shall review selected coursework. ~~Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course.~~²² The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. ~~those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(e).~~

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

²² The board no longer has a continuing education committee.

~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.²³~~

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in Section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Authority cited: Sections 4005, 4206 and 4232, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course ~~coursework~~, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Article, each applicant for renewal of a pharmacist license shall submit ~~with the application for renewal~~ proof satisfactory to the ~~board~~ Board that, that the applicant has completed 30 hours of continuing education in the prior 24 months. ~~subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.~~

(b) All pharmacists shall retain their certificates of completion for four ~~(4)~~ years following completion of a continuing education course. ~~the program.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for ~~license~~ renewal on the grounds of emergency or hardship by applying to the ~~board~~ Board in writing, ~~on a~~

²³ Moved to Section 1732.1.

~~form provided for that purpose~~; setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board. ~~full Board of Pharmacy~~.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

AGENDA ITEM H

Memorandum

To: Licensing Committee

Date: September 7, 2004

From: Virginia Herold

Subject: Report on the Pharmacist Licensure
Examinations

1. Report on the Pharmacist Licensure Examinations

The board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004.

Here are statistics describing our examination program as of September 1, 2004:

- 2,303 applications have been received to take the California license exams
108 of these are retake applications

- 745 individuals have become licensed as pharmacists since mid-June

- 1,838 individuals have been made eligible to take the licensure examinations
94 individuals have also been requalified to take the exams (they failed one of the exams, and had to requalify)

- 1,368 individuals have been verified to the NABP as qualified to take the NAPLEX for California (includes score transfers)

- 1,299 CPJE examinations have been administered

- 17 regrades of the CPJE have been performed (resulting in no change in score)

- The CPJE's pass rate is 86 percent

2. Transfer of NAPLEX Scores to California after a State Licenses a Pharmacist

There are three ways that an individual may provide a NAPLEX score to the California Board of Pharmacy:

1. The individual becomes qualified by California as eligible to take the pharmacist licensure examinations, with California as the primary state.
2. The individual becomes qualified in another state to take the pharmacist licensure examination, but designates California as a “score transfer” state -- before he or she takes the NAPLEX. Then once California qualifies the individual as eligible to take the licensure examinations here, the NABP will transfer the score to the board.
3. The individual qualifies for the NAPLEX examination in another state and becomes licensed there. Later, at some point, the individual wants to become licensed in California. In some states, the state where the individual is licensed is willing to “assign” the NAPLEX score to California via a process the NABP calls “license transfer” (however, the applicant still needs to fulfill all other requirements for licensure in CA, including passing the CPJE).

Since January, the board has been using options 1 and 2 to obtain NAPLEX scores for eligible candidates.

Regarding option 3: recently, the NABP surveyed all other states regarding their willingness to accept a NAPLEX score from California, after an individual is licensed here. The NABP calls this “License Transfer” or “assignment of a score by licensure.” Thirty states responded and not all these states indicated that they are willing to do this.

Willing to accept an “assignment of NAPLEX score” from California are:

Yes:

No:

AK, DE, FL, HI, IL, KS
MN, MO, NE, NH, NY, ND, OH
OR, SD, TN, TX, VA, WI

AZ, AR, GA, ID, LA, MD, NV
PA, WA, WY

Those that answered yes indicated that they would accept the NAPLEX score earned after 1/1/04 for a pharmacist licensed in California – and they would allow a score earned in their state to be used by California for purposes of licensure. In such cases, these candidates would not need to retake the NAPLEX if they want to become licensed in the other state, although there may be other requirements for licensure (in California, the individual would still need to pass the CPJE if the NAPLEX score was earned after 1/1/04 and transferred here by an agreeable state).

For those states that answered no, there would be no sharing of NAPLEX scores unless a score transfer (option 2) was requested before the individual took the NAPLEX. Instead these candidates would need to retake the NAPLEX.

For those 19 states that didn't respond, the NABP and the board do not know whether NAPLEX scores could be transferred after licensure in one state to another state.

3. Restructuring of the Competency Committee

The Competency Committee develops and scores the CPJE. At the April Board Meeting, the board agreed with a Licensing Committee recommendation to restructure the Competency Committee into a two-tier structure – a core committee and a group of item writers.

The item writers would develop questions for the examination, and the core committee would select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

The board is now seeking to identify new members for the two committees. In the next board newsletter (projected date: November 2004), the board will seek nominations from interested pharmacists to serve in either capacity.

The item writers will meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline will be assigned. There will be no other meeting for this group of individuals.

The core committee will be slightly smaller than the current Competency Committee (if the current Competency Committee was fully appointed, there would be 29 members). The new structure is:

<u>Composition:</u>	<u>19 members</u>
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance of the core committee meetings will be a requirement, and those who miss a certain number of committee meetings each year will be asked to become item writers, where attendance at meetings is not necessary. There will be six two-day meetings annually.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed. Newer pharmacists are sought because the examination measures practice at the entry level with two years' pharmacist experience, not after 20 years of experience.

The board's president will appoint members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

The new committee structure should be in place early next year.

4. NAPLEX Item Writers

The National Association of Boards of Pharmacy periodically seeks item writers for the NAPLEX examination. The board is interested in forwarding to the NABP the names of individuals interested in serving as NAPLEX item writers. The NABP selects its item writers.

This opportunity will be discussed in the board's next newsletter as well.

5. Job Analysis Underway

The board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline.

The board last conducted a job analysis in 1999, so it is now time to conduct a new evaluation. In November, approximately 2,000 pharmacists will be sent questionnaires that include a number of task statements.

The pharmacists surveyed by the board will be asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses are confidential and will be compiled by the board's examination consultant. The board will use a system it has used in the past to provide CE credit to those who complete the analysis while maintaining the respondent's confidentiality.

A new content outline should be in place by February or March 2005, and all test items administered by mid-2005 will correspond to the new content outline. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.